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No. 98-1131

In The

Supreme Court of the United States

October Term, 1998

ANN WARDER, et al.,

Petitioners,

v.

DONNA E. SHALALA, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

AMICUS CURIAE BRIEF IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

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AMICUS CURIAE BRIEF IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Amicus Curiae[1] are twenty national disability-related organizations representing people with disabilities and chronic illnesses and the providers who serve them. These organizations are National Association for the Advancement of Orthotics and Prosthetics, American Orthotic and Prosthetic Association, American Academy of Neurology, American Academy of Physical Medicine and Rehabilitation, American Association for Respiratory Care, American Music Therapy Association, American Therapeutic Recreation Association, Brain Injury Association, Center on Disability and Health, Home Health Services and Staffing Association, National Association of People With AIDS, National Association of Private Schools for Exceptional Children, National Association of School Psychologists, National Council for Community Behavioral Healthcare, National Organization on Disability, National Parent Network on Disabilities, National Rehabilitation Association, NISH (formerly the National Industries for the Severely Handicapped), RESNA (formerly Rehabilitation Engineering Society of North America), and American Medical Rehabilitation Providers Association.

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[1] James P. Kelly, attorney for Petitioners, contributed, in part, to the preparation of this *Amicus Curiae* Brief. Petitioner OrthoConcepts made monetary contributions to the preparation and submission of this brief.

Collectively, the *Amicus Curiae* represent the interests of millions of individuals with severe physical and neurological disabilities which significantly impact their health and ability to function independently, and, within those populations, the thousands of patients with total or near total musculo-skeletal failure who reside in nursing homes and who need clinically effective complex or innovative braces which must sometimes be attached to medical or non-medical items or equipment due to the frailty of these patients and the inability to tolerate traditional orthopedic braces. Often these individuals can only reside in nursing homes due to the extensive nature of their physical impairments and the high level of rehabilitative care required by these patients. Some of the *Amicus Curiae* represent caregivers and suppliers of medical goods and services to these vulnerable patients.

In Health Care Finance Administration ("HCFA") Ruling 96-1 ("HCFAR 96-1"), the Secretary implemented a significant change in Medicare policy without any congressional direction to do so. Specifically, the Secretary restricted the meaning of "leg, arm, back, and neck braces" under the orthotics benefit to only those braces which "are used independently rather than in conjunction with, or as components of other medical or non-medical equipment." HCFAR 96-1 further deemed "braces" which are used in conjunction with other medical or non-medical equipment to be "durable medical equipment" ("DME").

Prior to the effective date of HCFAR 96-1, individuals with severe physical disabilities which resulted in complete or near-complete musculo-skeletal failure (hereinafter referred to as "catastrophically impaired" individuals)

who required that their braces be fabricated for use in conjunction with, or as components of, other medical or non-medical equipment were entitled to this benefit if their physician prescribed the bracing system. After the effective date of HCFAR 96-1, catastrophically impaired individuals who resided in nursing homes were denied this Medicare entitlement.

HCFAR 96-1 removes such orthotic braces from the personal Medicare benefits (namely, those under Medicare Part B) of such catastrophically impaired patients in nursing homes. There is no other benefit under Medicare which could reliably provide an alternative source of such braces to catastrophically impaired patients in nursing homes. This deprivation caused by HCFAR 96-1 occurs because DME is not a covered personal benefit under Medicare to residents of nursing homes, while orthotic bracing is a covered personal benefit.

If not an outright abrogation of the Medicare "braces" benefit for catastrophically impaired residents of nursing homes who need orthotic treatment, then, the *Amicus Curiae* contend, HCFAR 96-1 is a substantive change in the law and required public notice and comment prior to restricting coverage for these devices.

The *Amicus Curiae*, therefore, request the opportunity to represent the interests of thousands of catastrophically impaired individuals who reside in nursing homes and need complex or innovative orthotic braces, including persons with multiple sclerosis, amyotrophic lateral sclerosis ("ALS"), cerebral palsy, stroke, paralysis, traumatic brain injury, and a host of other disabling conditions and chronic illnesses, and who are adversely impacted by

being deprived of clinically effective braces. Because HCFAR 96-1 deprives these individuals who live in nursing homes of the Medicare benefit of clinically effective braces, the question of whether HCFAR 96-1 is valid is "an important question of federal law that has not been, but should be, settled by this Court." Rules of the Supreme Court 10 (c). Further, because HCFAR 96-1 bindingly redefines the explicit statutory term of "brace" or "orthotic" without explicit congressional direction to do so, and thus, a departure from congressional Medicare policy, the *Amicus Curiae* support Petitioners in their assertions that Congress could not have intended the Secretary to implement such a significant change in Medicare policy without congressional direction to do so or without the proper notice and comment process established under the Administrative Procedure Act.

SUMMARY OF ARGUMENT

Section 1861(s)(9) of the Social Security Act (42 U.S.C. § 1395x(s)(9)) specifically states under the Medicare orthotics benefit that beneficiaries are entitled to "leg, arm, back, and neck braces." No court has been asked to define what constitutes a "brace" under the Social Security Act.

In HCFAR 96-1, the Secretary, without congressional direction to do so, restricted the meaning of "leg, arm, back, and neck braces" to only those braces which "are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment."

HCFAR 96-1 further simply deemed "braces" which are used in conjunction with other medical or non-medical equipment to be durable medical equipment ("DME"). By such deeming, HCFAR 96-1 transforms, for example, an arm brace mounted on an exoskeletal base or on a wheelchair from a "brace" to "DME".

Certain residents of nursing homes have such complete musculo-skeletal failure that their braces must be fabricated for use in conjunction with, or as components of, other medical or non-medical equipment. For example, braces for such catastrophically impaired patients often must be anchored to or mounted on medical or non-medical equipment (such as an exoskeletal base or a wheelchair) in order for the orthotic treatment to properly perform its bracing function. Traditional braces that are attached only to the patient often cannot be tolerated by this population due to musculo-skeletal frailty and the likelihood of skin breakdown. Simply because a Medicare beneficiary resides in a nursing home and may not be able to ambulate is no reason to effectively deny the patient the orthotic benefit needed to treat muscle contractures, decubitus ulcers (commonly known as "bedsores"), and other musculo-skeletal abnormalities or failures that prevent the patient from being able to sit upright, breathe and swallow properly, minimize pain, avoid further musculo-skeletal deformity, interact with other people, and live with some modicum of dignity.

HCFAR 96-1 removes such braces from the personal Medicare benefits (namely, those under Medicare Part B) of such catastrophically impaired patients in nursing homes. There is no other benefit under Medicare which could reliably provide an alternative source of such braces to catastrophically impaired patients in nursing

homes. This deprivation caused by HCFAR 96-1 occurs because DME is not a covered personal benefit under Medicare to residents of nursing homes.

If not an outright abrogation of the Medicare "braces" benefit for catastrophically impaired residents of nursing homes who need braces, then, *Amicus Curiae* contend, HCFAR 96-1 is a substantive change in the law and required public notice and comment prior to implementation of this significant change in coverage policy.

The District Court ruled, *inter alia*, that HCFAR 96-1 effected a substantive change in Medicare law, which required prior notice and comment under the Administrative Procedure Act and the Social Security Act. The District Court enjoined the Secretary from enforcing HCFAR 96-1. The Court of Appeals reversed the District Court. Petitioners appealed the decision of the First Circuit Court of Appeals. The *Amicus Curiae* join Petitioners in their appeal and incorporate Petitioners' Appendix by this reference.

ARGUMENT

A. **Is it clear that Congress intended the Medicare "braces" benefit to be restricted by an administrative interpretation which deprives residents of nursing homes from a personal Medicare entitlement to braces which are used in conjunction with other medical or non-medical equipment (such as an arm, leg, back or neck brace attached to a wheeled base or to a wheelchair)?**

The *Amicus Curiae* submit that it is clear that Congress did not intend for braces to be denied to catastrophically impaired Medicare beneficiaries who are

residents of nursing homes. Yet, such denial is precisely the effect of HCFAR 96-1. Because of its impact on the most vulnerable members of society, the validity of HCFAR 96-1 raises an important question of federal law that has not been, but should be, settled by the Supreme Court. Rules of Supreme Court 10.

The above question and the *Amicus Curiae's* submitted answer provide a departure point for analysis of the validity of HCFAR 96-1 under *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984).

As Justice Scalia has noted in discussing *Chevron*, where

> Congress intended a particular result, but was not clear about it . . . what we have is genuinely a question of law, properly to be resolved by the courts.

Scalia, *Judicial Deference to Administrative Interpretation of Law*, 1989 DUKE L.J. 511, 516.

As Justice Scalia noted further in the same article,

> Here [referring to the question of how to determine whether the Congressional intent is clear or ambiguous] . . . is the chink in *Chevron's* armor – the ambiguity that prevents it from being an absolutely clear guide to future judicial decisions. How clear is clear?

Id. at 520.

Petitioners' case provides an opportunity for the Court to "fill the chink in *Chevron's* armor" by providing guidance to answer Justice Scalia's question of "How clear is clear?" in assessing whether Congress has spoken clearly enough, so as to preclude an administrative rule

(such as HCFAR 96-1) which frustrates Congress' intent to provide braces to patients in nursing homes. The question of "How clear is clear?" is an important question of federal law which has not been, but should be, decided by the Supreme Court.

When Congress intends not to provide a benefit to patients in a nursing home, it does so plainly. It did so in denying durable medical equipment ("DME") benefits to patients in nursing homes by defining coverage for DME to be limited to use in a patient's "home" (which is defined as other than a hospital under 42 U.S.C. § 1395x(e)(1) or a skilled nursing facility under 42 U.S.C. § 1395i-3(a)(1)). 42 U.S.C. § 1395x(n). Congress has also shown that it is capable of expressing its intent that the Secretary further define DME, as it did when it required the Secretary to promulgate regulations defining a customized wheelchair. P.L. 101-508, § 4152(c)(4); H.R. No. 101-881, 101st Cong. 2nd Sess., 1990 USCCAN at 2770. Congress has shown no intent to limit the brace benefit by restrictive interpretations issued without notice and comment.

B. Is HCFA Ruling 96-1's ("HCFAR 96-1") limitation of the Medicare orthotic "brace" benefit under 42 U.S.C. § 1395x(s)(9) to only those braces "which are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment" a substantive change in the law which requires prior notice and comment under the Social Security Act ("SSA") and the Administrative Procedure Act ("APA")?

HCFAR 96-1 is a substantive (a/k/a "legislative") rule, rather than an interpretive rule because it

> . . . imposes obligations, the basic tenor of which is not already outlined in the law itself . . .

La Casa del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992). Among other burdens, an obligation imposed by HCFAR 96-1 which is not already outlined in the law is that HCFAR 96-1 deprives catastrophically impaired Medicare beneficiaries who reside in nursing homes of a right to braces, simply because the fabrication of their braces necessitates the use of such braces in conjunction with other medical or non-medical equipment.

Nowhere on the face of the Medicare brace benefit, set forth in 42 U.S.C. § 1395x(s)(9), did Congress hint at such a restriction. Because Congress made no mention of such a restriction, HCFAR 96-1 cannot be an interpretation of existing law. Therefore HCFAR 96-1 should have been published for notice and comment pursuant to the SSA and the APA. 42 U.S.C. § 1395hh and 5 U.S.C. § 553(b).

Nevertheless, the above question presents an important question of federal law that has not been, but should be, decided by the Supreme Court. As the First Circuit noted in Petitioner's case

> The line between a legislative or substantive rule and an interpretative one is, as many courts have noted, far from clear.

Warder v. Shalala, 149 F.3d 73, 79 (1st Cir. 1998), citing *e.g., Convaleciente*, 965 F.2d at 1177. *See also, What Constitutes "Interpretative Rule" of Agency So As to Exempt Such Action from Notice Requirements of Administrative Procedure Act* (5

U.S.C. § 553(b)(3)(A), 126 A.L.R. 347 (1995); Herz, *Deference Running Riot: Separating Interpretation and Law-making Under Chevron*, 6 ADMIN. L.J. (1992); Crouse, *Benten v. Kesser: The Time for Uniformity in the Application of Section 553 of the Administrative Procedure Act Has Come*, 7 ADMIN. L.J. (1993).

C. If HCFAR 96-1 is an interpretative ruling published without prior notice and comment, is it entitled to judicial deference?

This is an important question of federal law that has not been, but should be, settled by the Supreme Court. *Chevron* involved a rule issued with prior notice and comment. Such prior notice and comment was calculated to involve appropriate political participation. *See* Scalia, id. at 517. HCFAR 96-1's promulgation without notice and comment raises an important issue of whether judicial deference should be given to an agency interpretation made without prior public, outside expert, or political involvement and accountability as contemplated by the notice and comment provisions of APA and the SSA.

Moreover, the Supreme Court should decide this question because

> a United States court of appeals has entered a decision [on this question] in conflict with the decision of another United States court of appeals on the same important matter.

Rules of Supreme Court 10(a).

As the First Circuit noted below in Petitioner's case:

> A threshold question is what deference is owned to an interpretative rule such as HCFAR 96-1. *The Supreme Court has not expressed a view on whether or to what extent the Chevron framework . . . applies to interpretive rather than legislative rules, and other circuits are split on the issue."* (Emphasis supplied), *citing* at footnote 8: *Compare Trans Union Corp. v. FTC*, 81 F.3d 228, 230 (D.C. Cir 1996) ("[W]e have extended *Chevron* deference to agency interpretive rules . . . indeed, the rule at issue in *Chevron* itself appears to have been interpretive."), *and, Elizabeth Blackwell Health Ctr. For Women v. Knoll*, 61 F.3d 170 (3d Cir. 1995) (equal deference), *and, Garcia v. Secretary of Health & Human Servs.*, 46 F.3d 552, 556 (6th Cir. 1995) (same) *with Atchison, Topeka & Santa Fe Ry. Co. v. Pena*, 44 F.3d 437, 442 (7th Cir. 1994) (en banc) (concluding that interpretive rules are "underserving of deference under *Chevron*").

The question of whether deference should be extended to HCFAR 96-1 was not answered by *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995). *Guernsey* involved a narrow gap "unaddressed by the otherwise comprehensive regulations on [a] particular subject." Id. at 97. In contrast to *Guernsey's* gap, HCFAR 96-1 broadly addresses a whole subject matter of an enumerated Medicare benefit, namely "braces" as set forth in 42 U.S.C. § 1395x(s)(9), about which there are few regulations. Moreover, HCFAR 96-1 raises broad policy questions of important federal law of why place of residence (namely, in a nursing home or not) should deprive catastrophically impaired Medicare beneficiaries of the particular types of

braces they need (namely, braces used in conjunction with other medical or non-medical equipment).

CONCLUSION

For the thousands of catastrophically impaired individuals residing in nursing homes who have been denied Medicare entitlement to orthotic bracing prescribed by their physicians following the unauthorized and improper application of HCFAR 96-1, the *Amicus Curiae* respectfully request that the Supreme Court issue a Writ of Certiorari to Petitioners.

This 12th day of March 1999.

Respectfully submitted,

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